REMARKS

Status of the Claims:

Claim 1 has been amended. Claims 63-67 have been added. After amending the claims as set forth above, claims 1-23 and 49-67 are now pending in this application.

General Remarks:

Claim 1 has been amended to fix an obvious typographical error.

I. Claim Rejections – 35 U.S.C. § 103

A. The Barry and Tu References

Claims 1-11, 14-23, and 49-62 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (US Pat. Appln. No. US2002/0077592 A1) and Tu et al (USPN 6,053,913) (Tu). These rejections are respectfully traversed in view of the claims as amended herein.

Independent claim 1 recites a method for mitigating restenosis at a trauma site at which a stent is located within the vasculature comprising:

> positioning a catheter adjacent the trauma site;
> extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent; and
> delivering a restenosis mitigating drug to the trauma site through the catheter
> wherein the sensor comprises an analyte sensor, physiological parameter sensor, biological parameter sensor, biochemical parameter sensor, or chemical parameter sensor.

(Similar features are found in independent claim(s) 52.)

Claim 1 is neither taught, suggested, nor rendered predictable by the Barry and Tu references and the Barry and Tu references, alone or in the combination suggested by the

Examiner. In particular, claim 1 recites a method for mitigating restenosis at a trauma site at which a stent is located within the vasculature including, among other features, extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent.

Thus, a sensor is extended (i) **through both** the stent and **the catheter** (ii) to a position located **both outside the stent** and outside the catheter. The Barry and Tu references do not disclose or suggest a method for mitigating restenosis at a trauma site at which a stent is located within the vasculature, as recited in claim 1, including these features

According to the Examiner, the Barry reference discloses:

> [A] replenishable stent and drug delivery system (see figures 1-16 and paragraphs at [0002]-[0048] generally, specific embodiments at [0067]-[0097]). Barry discloses a method for mitigating restenosis at a trauma site (where a stent is located) within the vasculature comprising: positioning a balloon catheter adjacent, interior to the stent, before or after a stent procedure, at a trauma site; and extending a sensor through a lumen in the catheter and through the stent (see element 255 and figures 11,13-15); and delivering a restenosis mitigating drug through apertures in the balloon catheter, upstream to the trauma site. The Barry sensor (255) sensing element is located on one side of and is spaced from the stent (as in figure 13) and the outlet of the catheter is located on the opposite side of the stent at which the sensing element is located, so that the stent is between the outlet and sensor. Barry discloses the balloon catheter abuts a wall of the vasculature at the trauma site after the balloon catheter is expanded and also adjusting the flow rate and dispersal pattern of the restenosis mitigating drug. Barry further discloses using a restenosis mitigating agent or drug, which would include the use of insulin, nitric oxide, antibody, steroid, interleukin, blood thinner, ect. [sic] (see paragraph [0075]).

See p. 3 ll. 5-21 of the Office Action dated July 8, 2009 (*Office Action*). However, the cited portions do not address each of the features previously discussed. As acknowledged by the Examiner, the Barry reference does not disclose the step of extending the sensor "through the

stent to a position located outside of the catheter and outside of the stent" (as added in the applicant's most recent amendments). *See* p. 4 ll. 1-3 of *Office Action*. As a result, the Examiner cites the Tu reference, which as the Examiner argues, teaches:

> [I]t is known to use the step of extending the sensor through the stent to a position located outside of the catheter and outside of the stent (see Tu figure 3) as set forth in paragraphs beginning at column 5 lines 20-27, to provide the surgeon a measurement of tissue temperature. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Barry with the step of extending the sensor "through the stent to a position located outside of the catheter and outside of the stent" as taught by Tu, since such a modification would provide the method with the step of extending the sensor "through the stent to a position located outside of the catheter and outside of the stent" for providing the surgeon a measurement of tissue temperature.

See p. 4 ll. 3-13 of *Office Action*.

However, the combination suggested by the Examiner would **destroy** the device disclosed in the Barry reference. In particular, the Barry reference discloses a temperature sensor (235) located inside of a balloon (235) carrying a stent (36) and inside of catheter (230). *See, e.g.*, FIGS. 13 and 14 of the Barry reference. In more detail, the Barry reference discloses providing a heat treatment by heating liquid (234) located inside of the balloon. *See* para. [0088] and FIG. 14 of the Barry reference. Heating the liquid induces thermal coagulation of aneurysmal wall (223). *See* para. [0089] of the Barry reference. To regulate the temperature of the liquid accurately, a feedback control signal is required: the temperature sensor, which is positioned in the liquid in the balloon, provides this feedback control signal. *See* para. [0089] of the Barry reference; *see also* FIG. 14 of the Barry reference (showing the temperature sensor as being located inside the balloon). Locating the temperature sensor anywhere but within the

liquid in the balloon carrying the stent would prevent the temperature sensor from measuring and regulating the temperature of the heated liquid within the balloon – the very purpose for including the temperature sensor.

Moreover, the Tu reference does not address the distinction between claim 1 and the Barry reference. The Tu reference fails to disclose a sensor extended (i) **through both** the stent and **the catheter** (ii) to a position located **both outside the stent** and outside the catheter. Indeed, the Tu reference discloses: a temperature sensor (27) is provided on a stent (11) in contact with human tissue. *See, e.g.*, col. 5 ll. 20-27; col. 7 ll. 17-26; FIG. 3 of the Tu reference. In particular, the Tu reference discloses providing an ablation treatment by heating contacted tissue with a stent having an RF current. *See, e.g.*, col. 5 ll. 9-20 of the Tu reference. To measure the temperature of the tissue and regulate the RF current accurately, a feedback control signal is required: the temperature sensor, which is positioned between the catheter and the stent (see Fig. 3), which is supported around the catheter (col. 5 ll. 66-67) measure the heated tissue, provides this feedback control signal through an associated external wire (28). *See, e.g.*, col. 5 ll. 20-25; col. 7 ll. 12-26; *see also* FIG. 3 of the Tu reference (showing the temperature sensor on the stent as well as the associated wiring positioned outside the stent and the catheter (9) before entering only the stent). Figures 2 and 3 of the Tu reference clearly show the wire is completely external (i.e., never enters) the catheter (9), and thus does not extend into – much less through – the catheter (or the lumen (10) of the catheter). Because the wire is external the catheter it can only connect with the temperature sensor if it is likewise external or outside of the catheter. *See, e.g.*, Fig. 3 of the Tu reference (illustrating that the temperature sensor is positioned between the

catheter and the stent, and outside of the stent). Therefore, the temperature sensor necessarily must be outside of the catheter.

Because the temperature sensor of the Tu reference is outside the catheter (without it or the associated wire ever being inside the catheter or lumen of the catheter), the temperature sensor **neither** extends into nor through the catheter.

Furthermore, because the temperature sensor is located between the catheter and the stent, as discussed above, the temperature sensor is not located outside the stent.

Thus for the reasons above, the Tu reference does not disclose a sensor extended (i) **through both** the stent and **the catheter** (ii) to a position located both **outside the stent** and outside the catheter.

To establish a prima facie obviousness of a claim invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Because none of the references disclose or suggest the recited features, there can be no prima facie obviousness by seeking to combine these references. Thus, claim 1 is believed to be allowable.

In addition, claim 58 recites: "wherein extending the sensor through the lumen in the catheter and through the stent comprises extending the sensor through a proximal end of the stent and a distal end of the stent opposite the proximal end." Neither the Barry reference nor the Tu reference discloses or suggests these features.

In particular, the Examiner argues:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Barry with the step of extending the sensor 'through the stent to a position located outside of the catheter and outside of the stent' as taught by Tu, since such modification would

provide the method with the step of extending the sensor 'through the stent to a position located outside of the catheter and outside of the stent' for providing the surgeon a measurement of tissue temperature.

See p. 4 ll. 7-13 of *Office* Action.

However, the Federal Circuit has held that with respect to a rearrangement of parts, which is analogous to a rearrangement of steps: "The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims . . . is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device." *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (BPAI 1984); MPEP 2144.04 VI.C. Here, the cited references not only fail to provide any reason or motivation to extend a sensor through a proximal end of a stent and a distal end of the stent opposite the proximal end, but doing so, as discussed above, would destroy the each of the devices of the Barry reference and the Tu reference.

Claims 2-11, 14-23, and 49-51, and 55-58 depend from claim 1 (directly or indirectly) and are believed to be allowable for at least the same reasons as claim 1 is believed to be allowable. Claims 53, 54, and 59-62 depend from claim 52 (directly or indirectly) and are believed to be allowable for at least the same reasons as claim 52 is believed to be allowable. Accordingly, the rejections of claims 1-11, 14-23, and 49-62 are respectfully traversed.

B. The Barry, Tu, and Silver References

Claims 12 and 13 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Barry, Tu, and Silver (USPN 6,442,413). These rejections are respectfully traversed in view of the claims as amended herein.

Claims 12 and 13 are believed to be allowable at least for the reasons previously discussed with respect to their parent claims. Specifically, as discussed above, the Barry and Tu references do not disclose a system for mitigating restenosis at a trauma site at which a stent is located within the vasculature including a sensor that is extended (i) **through both** the stent and **the catheter** (ii) to a position located **both outside the stent** and outside the catheter.

According to the Examiner, the Silver reference discloses "an implantable glucose sensor that can be used for implantation in a blood vessel." *See* p. 4 l. 20-21 of *Office Action*. However, the Silver reference does not discuss the recited feature.

To establish a prima facie obviousness of a claim invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Because none of the references disclose or suggest the recited features, there can be no prima facie obviousness by seeking to combine these references. Thus, claims 12 and 13 are believed to be allowable. Accordingly, the rejections of claims 12 and 13 are respectfully traversed.

C. The Barry and Tu References

Claims 4 and 19-23 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Barry and Tu. These rejections are respectfully traversed in view of the claims as amended herein.

Claims 4 and 19-23 are believed to be allowable at least for the reasons previously discussed with respect to their parent claims. Specifically, as discussed above, the Barry and Tu references do not disclose a system for mitigating restenosis at a trauma site at which a stent is located within the vasculature including a sensor that is extended (i) **through both** the stent and **the catheter** (ii) to a position located **both outside the stent** and outside the catheter.

According to the Examiner, the drugs recited in claims 4 and 19-23 are not disclosed in the Barry and Tu references, but are obvious. *See* p. 5 l. 14-17 of *Office Action*. However, this argument does not address the recited feature.

To establish a prima facie obviousness of a claim invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Because none of the references disclose or suggest the recited features, there can be no prima facie obviousness by seeking to combine these references. Thus, claims 4 and 19-23 are believed to be allowable. Accordingly, the rejections of claims 4 and 19-23 are respectfully traversed.

II. New Claims:

Claims 63-67 are added to further protect additional features of the present invention

Claim 63 generally recites, among other features, wherein blood flows through the vasculature in a direction through a first end of the stent and then through a second end of the stent opposite the first end of the stent; and wherein extending the sensor through the lumen in the catheter and through the stent comprises extending the sensor through the first end of the stent and the second end of the stent opposite the proximal end. This claim is supported by the original application, for example, in Fig. 1. This claim is not disclosed in the cited reference(s).

Moreover, this claim is believed to be allowable at least for the reasons of its parent claims and/or the reasons previously discussed.

Claim 64 generally recites, among other features, wherein extending the sensor through the lumen in the catheter and through the stent comprises extending the sensor through a proximal end of the stent and a distal end of the stent through which blood flows out of, the distal end of the stent opposite the proximal end of the stent. This claim is supported by the original application, for example, in Fig. 1. This claim is not disclosed in the cited reference(s). Moreover, this claim is believed to be allowable at least for the reasons of its parent claims and/or the reasons previously discussed.

Claim 65 generally recites, among other features, wherein extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent comprises extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent such that the sensor is spaced apart from the stent. This claim is supported by the original application, for example, in Fig. 1. This claim is not disclosed in the cited reference(s). Moreover, this claim is believed to be allowable at least for the reasons of its parent claims and/or the reasons previously discussed.

Claim 66 generally recites, among other features, wherein extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent comprises extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent such that the sensor is spaced apart from the stent. This claim is supported by the original application, for example, in

Fig. 1. This claim is not disclosed in the cited reference(s). Moreover, this claim is believed to be allowable at least for the reasons of its parent claims and/or the reasons previously discussed.

Claim 67 generally recites, among other features, the stent having a generally cylindrical shape, the stent having a longitudinal axis and two opposed ends at opposite ends of the longitudinal axis, each of the two opposed ends being open to a generally hollow interior of the stent; wherein extending the sensor through the lumen in the catheter and through the stent comprises extending the sensor through one end of the two opposed ends of the stent and out the other end of the two opposed ends of the stent. This claim is supported by the original application, for example, in Fig. 1. This claim is not disclosed in the cited reference(s). Moreover, this claim is believed to be allowable at least for the reasons of its parent claims and/or the reasons previously discussed.

III. Conclusion:

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of

papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 10/7/09

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